REMARKS

Reconsideration is requested.

Claims 1-23, 25 and 27-47 have been canceled, without prejudice. Claim 24 has been amended to advance prosecution, for the reasons described below. Claims 48-52 are directed to alternative embodiments of the sequences of SEQ ID NO:24. The new claims are based on the disclosure at page 15, lines 28-34, for example. No new matter has been added. Claim 26 has been amended to fall within the elected subject matter. Examination of the same is requested.

Attached is a copy of the Information Disclosure Statement filed July 12, 2001, with the associated papers. Consideration of the attached and return of an initialed copy of the Information Disclosure Statement as an indication and consideration of the same, is requested.

The Rule 75 objection of claim 26 is obviated by the above as claim 26 now is dependent on claim 24 and is of a different scope. Withdrawal of the Rule 75 objection to claim 26 is requested.

The Section 112, first paragraph, rejection of claims 24 and 25 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

The Examiner has argued that the specification does not reasonably provide enablement for polypeptide variants having at least 70% sequence identity to SEQ ID NO: 24. The Examiner suggests that it could not be predicted that a variant protein sharing such a partial homology with a disclosed protein would function in the same

manner as the disclosed protein. However, as noted by the Examiner, claim 24 part (iii) does not require any function of the variant polypeptides.

Claim 24 is directed to a method of raising an immune response against a mycobacterium by administering particular polypeptides. The ability of a variant polypeptide to produce such an immune response is unrelated to its ability to function in the same way as the polypeptide of SEQ ID NO: 24. Claim 24 part 3 merely requires that the variant polypeptide is sufficiently similar to the polypeptide of SEQ ID NO: 24 such that the immune response raised against the variant polypeptide would also be effective against the mycobacterium, for example a mycobacterium expressing a polypeptide according to SEQ ID NO: 24.

In order to clarify this further, part (iii) of claim 24 has been amended to include the simple functional test that the variant must be capable of stimulating an immune response against the mycobacterium. That is, the variant must be sufficiently similar to SEQ ID NO: 24 that the immune response stimulated by the variant will act on the same mycobacterium as the immune response stimulated by the polypeptide of SEQ ID NO: 24. For example, when the immune response takes the form of antibody production, at least some of the antibodies generated in response to the variant of part (iii) are also capable of binding the mycobacterium.

As is clear from the application, it would be straightforward for one of ordinary skill in the art to determine whether administration of a particular polypeptide of the invention had actually been successful in raising a suitable immune response. For example, as described at page 17 lines 27 to 31, polypeptides or labelled polypeptides of the invention may be used in serological or cell mediated immune assays for the

detection of immune reactivity to such polypeptides using standard protocols. Suitable assays are further described from page 17 line 32 through to the end of page 18.

Applicants therefore submit that one of ordinary the skill in the art would be able to practice the claimed invention without undue experimentation. Withdrawal of the Section 112, first paragraph rejection stated on page 3 of Paper No. 12 is requested.

The Section 112, first paragraph "written description", rejection is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

The Examiner has argued that the specification provides sufficient written description only for SEQ ID NO: 24. That is, that there is allegedly insufficient written description for the embodiments described in parts (ii), (iii) and (iv) of claim 24. Applicants respectfully submit that the claims are supported by an adequate written description.

The Examiner has provided a number of definitions of what would provide a suitable written description for a DNA molecule. However, it is noted that claim 24 now pending does not refer to DNA molecules but to polypeptides. In any case, claim 24 does provide a description of the amino acid sequence claimed. The Examiner has suggested that "the species specifically disclosed are not representative of the genus because the genus is highly variant". See, page 8 of Paper No. 12. However, the variants of claim 24 are all defined specifically in relation to their amino acid sequence. Claim 24 provides the sequence of SEQ ID NO: 24 and provides three specifically defined classes of variants of that sequence. The present application does therefore provide "a precise definition, such a by structure, formula, chemical main, or physical

properties," as quoted by the Examiner on page 7 of Paper No. 12, and not a mere wish or plan for obtaining the claimed invention. As explained above, the claims also provide a simple functional test to define suitable variant sequences.

As also explained above, the invention does not relate to polypeptides *per se*, but to the ability of these polypeptides to stimulate an immune response which can act against a mycobacterium, in particular a mycobacterium that expresses the polypeptide of SEQ ID NO: 24. However, as explained above, it is not necessary that the immune response is stimulated by a polypeptide consisting essentially of SEQ ID NO: 24. Clearly, a polypeptide comprising the sequence of SEQ ID NO: 24 would be equally capable of generating a suitable immune response. For example, a polypeptide comprising SEQ ID NO: 24 may stimulate a number of immunoglobulins. However, it is likely that at least some of these would be specific to epitopes within the sequence of SEQ ID NO: 24 and would therefore bind to the same epitopes on the mycobacterium as the immunoglobulins raised against the original SEQ ID NO: 24 polypeptide.

Similarly, a fragment of SEQ ID NO: 24 comprising at least 12 amino acids and an epitope, or a polypeptide having at least 70% amino acid identity to SEQ ID NO: 24 over 30 or more contiguous amino acids would also produce an immune response which is likely to react against the same epitopes on the mycobacterium as an immune response raised against a full length SEQ ID NO: 24 polypeptide.

The variants listed in claim 24 therefore have the same effect in the claimed method as the polypeptide according to SEQ ID NO: 24 itself. What is important here is that the variant is sufficiently similar to SEQ ID NO: 24 to be able to produce an immune response that is active against the polypeptide of SEQ ID NO: 24, and will therefore

target the same epitopes on the mycobacterium as an immune response that has been raised against SEQ ID NO: 24 itself.

The Examiner has referred to Fiddes v. Baird (30 USPQ2d 1481, 1483) in which claims directed to mammalian FGFs were found unpatentable due to lack of written description for the broad class because the specification provided only the bovine sequence. Applicants submit that the facts of the present application are is very different from those considered by the court in Fiddes. Specifically, starting from a bovine sequence, the provision of further mammalian FGFs would require a substantial amount of experimentation on the part of the skilled person. The sequences of further mammalian FGFs could not be derived in a straightforward manner from the bovine sequence. However, in the present case, the variant polypeptides claimed are defined specifically in relation to the amino acid sequence of SEQ ID NO: 24. The ordinarily skilled person could clearly derive variant polypeptide sequences falling within the scope of claim 24 part (ii), part (iii) and part (iv) from SEQ ID NO: 24 given in the application. Such sequences could be derived from the existing sequence and would require little or no further experimentation.

The requirements for written description are therefore believed to be met and withdrawal of the Section 112, first paragraph and "written description", rejection is requested.

The Section 112, second paragraph, rejection of claims 24 and 25 is, to the extent not obviated by the above, traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

The Examiner has objected to the term "administering an effective amount of". Claim 24 has been amended to specify that the polypeptide is administered to said human or animal. It is submitted that this amendment overcomes the Examiner's objection.

The Examiner has objected to the term "epitope". Applicants respectfully submit that this term would be clear to one skilled in the art. The term "epitope" would be well known to one skilled in the art as referring to an antigenic determinant, for example one capable of generating an antibody. The term epitope is clearly defined in more detail in the application at, for example, page 16 lines 17 to 36. Further, as explained above, claim 24 relates to a method of raising an immune response. It would therefore be clear to one of skill in the art that reference to an epitope in part (iv) of this claim relates to an epitope that may be used in the raising of such an immune response.

The Examiner has objected to the phrase "which method comprises". This has been amended to read "the method comprising". It is believed that this amendment overcomes the Examiner's objection.

Withdrawal of the Section 112, second paragraph, rejection is requested.

The applicants acknowledge, with appreciation, the Examiner's indication of claims 24 and 25 are free of the art of record to the degree they read on polypeptides comprising SEQ ID NO:24. See, page 9 of Paper No. 12.

The applicants respectfully submit that the claims are in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned if anything further is required in this regard.

Respectfully submitted,

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